**Study Title:** Serum concentration of joint-specific biomarkers from the venous drainage of the lower limb may improve in the interpretation of acute and chronic degenerative knee and ankle joint disease (**The SORE study**)

**PARTICIPANT INFORMATION SHEET**

Research Ethics Reference: FMHS 170-1122

Version 1.2 Date: 28/06/2023

We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. One of our team will go through the information sheet with you and answer any questions you have. Please take time to read this carefully and discuss it with others if you wish. Ask us anything that is not clear.

**What is the purpose of the research?**

You are invited to take part in a research project about changes to your joints and how we can better understand them. It is running at the University of Nottingham. The study aims to understand the how proteins in the blood might show joint damage. We would like to know if these small proteins are different if blood samples are taken from different parts of the body or if they change following exercise.

**Why have I been invited to take part?**

You have been chosen either because you have had an recent injury, a diagnosis of osteoarthritis or someone without any joint problems. We would like to invite approximately 30 people into this study, ten with a recent injury, ten with osteoarthritis, and ten without any known joint problems.

**Do I have to take part?**

It is up to you to decide if you want to take part in this research. We will describe the study and go through this information sheet with you to answer any questions you may have. If you agree to participate, we will ask you to sign a consent form and will give you a copy to keep. However, you would still be free to withdraw from the study at any time, without giving a reason, simply let the research team know.

**What will happen to me if I take part?**

A researcher will contact you to go over the information sheet, explain the procedures, and go through a pre-screening with you to check if it is safe for you to participate. If you agree to take part in the study, you will be asked to attend a single visit at the School of Medicine at the University of Nottingham. Please bring with you a pair of shorts to wear for the study visit.

Upon arrival, we will talk you through the study procedures and give you chance to ask any questions. At this time, you will be asked a few questions about yourself and your medical history. If you are still happy to take part, then you will then be asked to sign a consent form.

Once the research team have checked that you can perform the study, a blood sample will be taken from the inside of your elbow. Another blood sample will be taken from your leg, in the middle of your thigh. A small needle will used to take the blood tests and a tourniquet will be applied during this process.

The second part of the study will measure the changes following physical activity, so if you are able, we will ask you to sit on a seated cycling machine for approximately ten minutes until you are slightly out of breath and your heart is beating a bit harder. Once you have reached this point, we will repeat the blood tests from your arm and from your leg.

Finally, we will use a handheld ultrasound scanner to look at your knees and take some measurements. This will not hurt and will involve some cold gel being applied to the skin.

Once those tests have been finished, you are free to leave. The entire visit will last approximately 45-60minutes.

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| **Test** | |
| **Blood Tests**  To measure approximately ten small proteins in the blood. This will require approx.. 4 small (one teaspoon each) bottles of blood, and is taken using a needle. | |
| **Cycling machine**  We will ask you to sit on an indoor cycling bike and cycle for approximately ten minutes until you are slightly out of breath and your heart is beating faster. | A person on a stationary bike  Description automatically generated with low confidence |
| Knee Pain Treatment - Private Ultrasound guided scan and injection | **Ultrasound scan**  A handheld ultrasound scanner will be used to take some measurements from your knees. This will be painless and involve some gel placed on the skin. |

1. **What are you measuring?**

We are measuring some small proteins in the blood which have been seen to raised in people with joint changes. We would like to know if these proteins are present in higher levels in different parts of the body or following physical activity. These proteins appear when the structure of the joint (cartilage or bone) changes, and if there is any inflammation present.

1. **Are there any risks in taking part?**

Disadvantages include the uncomfortable sensation when blood is being taken. Uncommonly, this can cause pain, bleeding, and rarely, infection. Finally, when performing exercise tests on an exercise bike, there is a very small risk of a medical problem, and there will be fully trained medical people present for that unlikely situation.

1. **Are there any benefits in taking part?**

There are no direct benefits for you as this is early research. We hope in the future that we will be able to improve the care for anyone with osteoarthritis, and this study is an important step toward that.

1. **Will my time/travel costs be reimbursed?**

Unfortunately, participants will not receive an inconvenience allowance to participate in the study Travel expenses will be offered for any visits incurred as a result of participation.

1. **What will happen to any samples I give?**

We would also like to seek your consent so that any remaining samples may be stored and used in possible future research – this is optional (please indicate you agree to this on the consent form). The samples will be stored with a code unique to you and securely at the University of Nottingham under the University’s Human Tissue Research Licence (no 12265).

Some of these future studies may be carried out by researchers other than the current team, including researchers working outside the University. Any samples or data used will be anonymised, and you will not be identified in anyway. If you do not agree to this any remaining samples will be disposed of in accordance with the Human Tissue Authority’s codes of practice.

1. **What happens to the data provided?**

Information will be collected from you at your visit regarding some basic personal information and some details about your medical history. This data will be stored securely on a computer with a password only known to the study team. After the study has finished, all the personal data will be deleted and only anonymous research data will be kept.

All research data and records will be stored for a minimum of 7 years after publication or public release of the work of the research.

We would like your permission to use anonymised data in future studies, and to share our research data (e.g. in online databases) with other researchers in other Universities and organisations both inside and outside the European Union. This would be used for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

Data sharing in this way is usually anonymised (so that you could not be identified)

1. **What will happen if I don’t want to carry on with the study?**

Even after you have signed the consent form, you are free to withdraw from the study at any time without giving any reason. Any personal data will be destroyed. If you withdraw we will no longer collect any information about you or from you but we will keep the anonymous research data that has already been collected and stored as we are not allowed to tamper with study records. This information may have already been used in some analyses and may still be used in the final study analyses.

1. **Who will know that I am taking part in this research?**

Data will be used for research purposes only and in accordance with the General Data Protection Regulations. Electronic storage devices will be encrypted while transferring and saving of all sensitive data generated in the course of the research. All such data are kept on password-protected databases sitting on a restricted access computer system and any paper information (such as your consent form, contact details and any research questionnaires) would be stored safely in lockable cabinets in a swipe-card secured building and would only be accessed by the research team.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). You can find out more about how we use your personal information and to read our privacy notice at: <https://www.nottingham.ac.uk/utilities/privacy.aspx/>

Designated individuals of the University of Nottingham may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines. With your consent, we will keep your personal information on a secure database in order to contact you for future studies.

1. **What will happen to the results of the research?**

The research will aim to be published in medical journals and will contribute toward the thesis of members of the research team. On successful submission of the thesis, it will be deposited both in print and online in the University archives, to facilitate its use in future research.

1. **Who has reviewed this study?**

All research involving people is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests.

1. **Who is organising and funding the research?**

Dr Stefan Kluzek, an Associate Professor at the University of Nottingham, is organising the research and it is funded by the University of Nottingham.

1. **What if there is a problem?**

If you have a concern about any aspect of this project, please speak to the researcher Dr Oliver O’Sullivan or the Principal Investigator Dr Stefan Kluzek, who will do their best to answer your query. The researcher should acknowledge your concern and give you an indication of how he intends to deal with it.

If you remain unhappy and wish to complain formally, you can do this by contacting the FMHS Research Ethics Committee Administrator, Faculty Hub, Medicine and Health Sciences, E41, E Floor, Medical School, Queen’s Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH or via E-mail: [FMHS-ResearchEthics@nottingham.ac.uk](mailto:FMHS-ResearchEthics@nottingham.ac.uk).

Please quote ref no: FMHS FMHS 170-1122

1. **Contact Details**

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Dr Oliver O’Sullivan

Academic Unit of Injury, Recovery and Inflammation Sciences

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